510(k) SUMMARY

DEC 2 0 2012

Bausch & Lomb PureVision (balafilcon A) Visibility Tinted Contact Lens

1.0 Submitter Information:

Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609
Contact: Nancy Fehrman
Senior Specialist, Global Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609
(585) 338-5735 (office)
(585) 338-0702 (fax)
Nancy.a.fehrman@bausch.com
Preparation Date: August 22, 2012

2.0 Device Name:

Trade Name:	Bausch & Lomb PureVision (balafilcon A) Visibility Tinted Contact Lens and Bausch & Lomb PureVision Toric (balafilcon A) Visibility Tinted Contact Lens
Common Name:	soft (hydrophilic) contact lens
Device Classification:	Class II (21 CFR 886.5925 (b) (1))

3.0 Predicate Device

The predicate device, OxyCor (balafilcon A) Visibility Tinted Contact Lens was selected to demonstrate substantial equivalence of the lens material, replacement schedules, and indications for use. OxyCor was cleared in 510(k) Premarket Notification K972454 on August 8, 1997.

4.0 Device Description

The Bausch & Lomb PureVision (balafilcon A) Visibility Tinted Contact Lens and the Bausch & Lomb PureVision Toric (balafilcon A) Visibility Tinted Contact Lens are soft hydrophilic contact lens. The lenses are made from the balafilcon A material, a copolymer of a silicone vinyl carbamate, N-vinyl-pyrrolidone, a siloxane crosslinker and a vinyl alanine wetting monomer, tinted blue with Reactive Blue Dye 246.

5.0 Intended Use

The Bausch & Lomb PureVision (balafilcon A) Visibility Tinted Contact Lens is indicated for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lenses may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in powers ranging from +20.00D to -20.00D for daily wear.

The Bausch & Lomb PureVision Toric (balafilcon A) Visibility Tinted Contact Lens is indicated for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters, that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in spherical powers ranging from +20.00D to –20.00D for daily wear.

6.0 Technological Characteristics (comparison to Predicate Device)

The subject devices are identical to the predicate device cleared under K972454. The table below shows a side-by-side comparison of the predicate device to the subject devices:

Property	OxyCor (balafilcon A) Visibility Tinted Contact Lens K972454	PureVision and PureVision Toric (balafilcon A) Visibility Tinted Contact Lens
Material	Balafilcon A	Same
Water Content	36%	
Physical/optical properties	Specific Gravity: 1.064 Refractive Index: 1.426 Surface Character: Hydrophilic	
Oxygen Permeability*	91 (Boundary and Edge Corrected) 101 (Boundary and Non-Edge Corrected) *Dk Units = $x10^{-11}$ $[cm^3O_2(STP)xcm]/(secxcm^2xmm\ Hg)@35°C$ (Polarographic Method)	
Color Additive	Reactive Blue Dye 246	
Manufacturing Method	Cast Mold	
Lens Design	Spherical and Toric	
Replacement	Frequent/Planned Replacement or Disposable Wear	
Base Curve	7.8 to 9.5 mm	
Diameter	13.5 to 15.0 mm	
Sphere Powers	+20.00D to -20.00D	
Cylinder Powers	0.00D to 10.00D	
Axis	0° to 180°	
Center Thickness	0.05 mm to 0.50 mm (varies with power)	
Difference		
Indications For Use	Exhibiting Astigmatism up to 10.00 diopters	Exhibiting Astigmatism up to 2.00 diopters (spherical design) or up to 5.00 diopters (toric design) (within currently cleared indications)

7.0 Summary of Non-Clinical Testing

There has been no change made to this device and therefore no non-clinical testing was required to demonstrate substantial equivalence to the predicate device.

8.0 Clinical Testing

There has been no change made to this device and therefore no clinical studies were required to demonstrate the safety or effectiveness of the subject device.

9.0 Substantial Equivalence

There has been no change made to the predicate device. The Indications for Use are within the range previously cleared under K972454. This submission only provides specificity to the Indications for Use for the eye care practitioners regarding prescribing these lenses for frequent/planned replacement wear or disposable wear and to limit the use within the currently cleared indications. Therefore, the Bausch & Lomb PureVision (balafilcon A) Visibility Tinted Contact Lens and the Bausch & Lomb PureVision Toric (balafilcon A) Visibility Tinted Contact Lens are substantially equivalent to the OxyCor (balafilcon A) Visibility Tinted Contact Lens cleared in 510(k) Premarket Notification K972454 on August 8, 1997.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 20, 2012

Bausch & Lomb, Incorporated
% Ms. Nancy A. Fehrman
Senior Specialist, Global Regulatory Affairs
1400 North Goodman Street
Rochester, New York 14609

Re: K122575
Trade/Device Name: Bausch & Lomb PureVision (balafilcon A) Visibility Tinted Contact Lens, Bausch & Lomb PureVision Toric (balafilcon A) Visibility Tinted Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL
Dated: December 7, 2012
Received: December 10, 2012

Dear Ms. Fehrman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122575

Device Name: Bausch & Lomb PureVision (balafilcon A) Visibility Tinted Contact Lens and Bausch & Lomb PureVision Toric (balafilcon A) Visibility Tinted Contact Lens

Indications for Use:

The BAUSCH & LOMB PureVision (balafilcon A) Visibility Tinted Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of 2.00 diopters or less, that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in spherical powers ranging from +20.00D to –20.00D for daily wear.

The BAUSCH & LOMB PureVision Toric (balafilcon A) Visibility Tinted Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not-aphakic persons with non-diseased eyes, exhibiting astigmatism of up to 5.00 diopters, that does not interfere with visual acuity. The lens may be prescribed for Frequent/Planned Replacement Wear or Disposable Wear in spherical powers ranging from +20.00D to –20.00D for daily wear.

FREQUENT/PLANNED REPLACEMENT WEAR
When prescribed for Frequent/Planned Replacement Wear, the BAUSCH & LOMB PureVision (balafilcon A) Visibility Tinted Contact Lens and BAUSCH & LOMB PureVision Toric (balafilcon A) Visibility Tinted Contact Lens is to be cleaned, rinsed and disinfected each time it is removed from the patient's eye and discarded after the recommended wearing period prescribed by the eye care practitioner. The lens may be disinfected using a chemical disinfection system.

DISPOSABLE WEAR
When prescribed for Disposable Wear, the BAUSCH & LOMB PureVision (balafilcon A) Visibility Tinted Contact Lens and BAUSCH & LOMB PureVision Toric (balafilcon A) Visibility Tinted Contact Lens is to be discarded after each removal.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K122575